PCT/EP2003/009299

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 27995P WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/009299	International filing date (*day/month/year*) 21 August 2003 (21.08.2003)	Priority date (*day/month/year*) 26 August 2002 (26.08.2002)
International Patent Classification (IPC) or national classification and IPC G01N 33/533		
Applicant F. HOFFMANN-LA ROCHE AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29 January 2004 (29.01.2004)	26 May 2004 (26.05.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/009299

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-10, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages 1-27, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 28, filed with the letter of 19 April 2004 (19.04.2004)

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP 03/09299

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-22, 24, 27	YES
	Claims	23, 25-26, 28	NO
Inventive step (IS)	Claims	1-22, 27	YES
	Claims	23-26, 28	NO
Industrial applicability (IA)	Claims	1-28	YES
	Claims		NO

2. Citations and explanations

1.) Reference is made to the following documents:

D1: US-B-6, 432, 722

D2: US-B-6,271, 041

D3: WO-A-02/00726

D4: M. Yang et al (2002) Anal. Chim. Acta 461, 141-146

D5: CA-A-2 313 144.

2.) The subject matter of claims 1-22 and 27 is not novel and inventive (PCT Article 33(2) and (3)). The reasons are as follows:

Documents D1 (the closest prior art) and D2 disclose methods (and devices) for detecting an analyte using electrochemiluminescence assays wherein the metal complex is electrochemically oxidized in the presence of tripropylamine (D1, column 1, line 1, to column 4, line 62; D2, column 9, line 48, to column 17, line 40, and figure 1).

Documents D3-D4 disclose methods (and devices) for generating electroluminescence by the electrochemical oxidation of acridan in the presence of a peroxide (D3, figures 1-2 and 7, and D4, abstract).

None of the above documents discloses a method wherein nascent hydrogen is used as a reducing agent for producing the excited metal complex state capable of chemiluminescence.

This improves the chemiluminescence yield and reduces susceptibility to interference when the method is used to detect analytes in a sample.

The disclosures of documents D1 to D4 would not have prompted a person skilled in the art, or provided him with a technical basis, to use nascent hydrogen as a reducing agent in the method according to document D1 in order to arrive at a method according to claims 1 (and 2-22).

The subject matter of independent claim 27 relates to a method for producing chemiluminescence according to which nascent hydrogen is used as a reducing agent and for analogous reasons is therefore not considered novel and inventive.

3.) For the following reasons the subject matter of claims 23, 25-26 and 28 is not novel within the meaning of PCT Article 33(2).

Documents D1-D4 (see above) disclose electrochemical devices comprising (i) agents for oxidizing a metal complex, (ii) agents for detecting chemiluminescence, and (iii) electrodes which can possibly be used for producing nascent hydrogen (see PCT Examination Guidelines, paragraph III-4.8). Documents D1 and D2 are prejudicial to the novelty of the subject matter of claims 23, 26 and 28 and documents D3 and D4 are prejudicial to the novelty of the subject matter of claims 23, 25-26 and 28.

4.) The subject matter of dependent claim 24 relates to a minor modification of the device according to claim 23 which would be straightforward to a person skilled in the art, especially since the resulting advantages are readily foreseeable, and is therefore considered novel (PCT Article 33(2)) but not inventive (PCT Article 33(3)) (see document D5, abstract, for an electrochemical cell in which the working electrode and the counter electrode are located in separate chambers).